K103470
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510(k) Summary
(per 2.1 CFR 807.92.(c))

JAN 11 2011

1. Applicant

B.J.ZH.F. Panther Medical Equipment Co. Ltd
Room 806, Peking Times Square B,
No.103 Huizhongli, Chaoyang District, Beijing, 100101; China

Date Prepared: 11/22/2010

2. Device Name

Trade Name: PANTHER Group of Surgical Staplers
Common/Usual Name: Stapler, Implantable
Classification Name: Implantable Staple
Regulation Number: 878.4750
Product Code: GDW
Classification: II
Panel: General & Plastic Surgery

3. Predicate Device

The PANTHER Group of Surgical Staplers includes:

- PANTHER Circular stapler
- PANTHER Hemorrhoidal Circular Stapler
- PANTHER Linear Stapler
- PANTHER Linear Cutter Stapler

are substantially equivalent to:

Subject Device	Predicate Device		
	Name	Company	510(k) Number
PANTHER Circular stapler	Autosuture™ EEA™ surgical Stapler	United States Surgical Corp. (USSC)	K062850
PANTHER Hemorrhoidal Circular Stapler	PROXIMATE PPH Hemorrhoidal Circular Stapler and Accessories	Ethicon Endo-Surgery, Inc	K030411
PANTHER Linear Stapler	AUTO SUTURE(R) TA PREMIUM(TM) UROLOGY STAPLER	United States Surgical Corp. (USSC)	K905106
PANTHER Linear Cutter Stapler	AUTO SUTURE DISPOSABLE GIA SURG. STAPLER	United States Surgical Corp. (USSC)	K801590

4. Intended Use

The PANTHER Surgical Staplers and there intended uses are as follows:

- **PANTHER Circular Stapler**

The Panther Circular staplers and accessories have application throughout the alimentary tract to create end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

- **PANTHER Hemorrhoidal Circular Stapler**

The PANTHER Hemorrhoidal Circular Stapler and accessories have application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

- **PANTHER Linear Stapler**

The PANTHER Linear Stapler can be applied in abdominal, thoracic and pediatric surgical procedures for transection or resection of tissue.

- **PANTHER Linear Cutter Stapler**

The PANTHER Linear Cutter Stapler can be applied in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.

5. Description of the Devices

The PANTHER Staplers were sterile(ETO), single-patient-use instruments which designed in reference to the general principles of surgical staplers. Each stapler/ instrument is activated by squeezing the handle firmly as far as it will go. Specifics for each stapler include:

- **PANTHER Circular Stapler**

The PANTHER Circular Stapler places a circular, double staggered row of titanium staples in the tissue and resects the excess tissue, thus creating a circular anastomosis. PANTHER Circular Stapler includes 4 series: FCSM, FCSME, FCSMF, and FCSLWBE.

- **PANTHER Hemorrhoidal Circular Stapler**

The PANTHER Hemorrhoidal Circular Stapler places a circular, double staggered row of titanium staples in the tissue and resects the excess tissue, thus creating a circular anastomosis. The Hemorrhoidal Circular Stapler set includes a Hemorrhoidal Circular Stapler, Suture Threader, Circular Anal Dilator and Purse-string Suture Anoscope. PANTHER Hemorrhoidal Circular Stapler includes 4 series: FCSS, FCSSME, FCSSWAE and FCSSWBE.

- **PANTHER Linear Stapler**

The PANTHER Linear Stapler places a double or triple staggered row of titanium staples used for mechanical suturing and closure of tissue, prior to the removal of excess tissue. and is available in 30 mm, 45 mm, 60 mm, 75 mm and 90 mm staple line lengths for use in various applications. The instrument may be reloaded during a single procedure but

cannot be reloaded more than seven times for a maximum of eight firings per instrument. PANTHER Linear Stapler includes 2 series: FLSL, FLSLE

- **PANTHER Linear Cutter Stapler**

The PANTHER Linear Cutter Staplers place two double staggered rows of titanium staples in organs and tissues to anastomose the internal tissues and simultaneously cut and divide between the two rows during surgical procedures. The PANTHER Linear Cutter Staplers is available in six staple line lengths (55, 60, 75, 80, 100 or110mm). The instrument may be reloaded during a single procedure but cannot be reloaded more than seven times for a maximum of eight firings per instrument. PANTHER Linear Cutter Stapler includes 2 series: SSAA, SSAB.

6. Summary of Performance Data

Bench testing was performed to verify the PANTHER Stapler's performance to internal specifications. In addition, bench testing was also performed to demonstrate that the PANTHER Stapler is substantially equivalent to the predicate devices.

7. Safety & Effectiveness

There are no substantial differences between the PANTHER Group of Surgical Staplers and the predicate devices. They have the same or similar indications for use. In addition, the minor differences in the technological characteristics do not raise issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Room 1606 Building 1, Jianxiang Yu,
No. 209 Bei Si Huan
Beijing, China 100083

JAN 1 1 2011

Re: K103470
Trade/Device Name: PANTHER Group of Surgical Staplers
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW, GAG
Dated: November 15, 2010
Received: November 26, 2010

Dear Chu Xiaoan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

JAN 1 1 2011

510(k) Number (if known): K103470

Device Name: PANTHER Group of Surgical Staplers

Indications For Use

510(k) Number (if known):

PANTHER Circular Stapler: The Panther Circular staplers and accessories have application throughout the alimentary tract to create end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries.

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PANTHER Linear Stapler: The PANTHER Linear Stapler can be applied in abdominal, thoracic and pediatric surgical procedures for transection or resection of tissue.

PANTHER Linear Cutter Stapler: The PANTHER Linear Cutter Stapler can be applied in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.

Prescription Use

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K103470